



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,836	04/26/2005	Armin Breitenbach	62804(46701)	8861
26646	7590	05/31/2007		
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			EXAMINER NAGUBANDI, LALITHA	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 05/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,836	Applicant(s) BREITENBACH ET AL.	
	Examiner Lalitha Nagubandi	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-69 is/are pending in the application.
- 4a) Of the above claim(s) 40-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/27/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Office Action

Status of Claims.

Claims 35 – 69 are pending. Claims 35 – 39 are considered for examination in this office action.

Response to Arguments

Applicant's arguments, see remarks, filed on February 21st, 2007 with respect to the rejection(s) of claim(s) 35-39 under 102 (b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

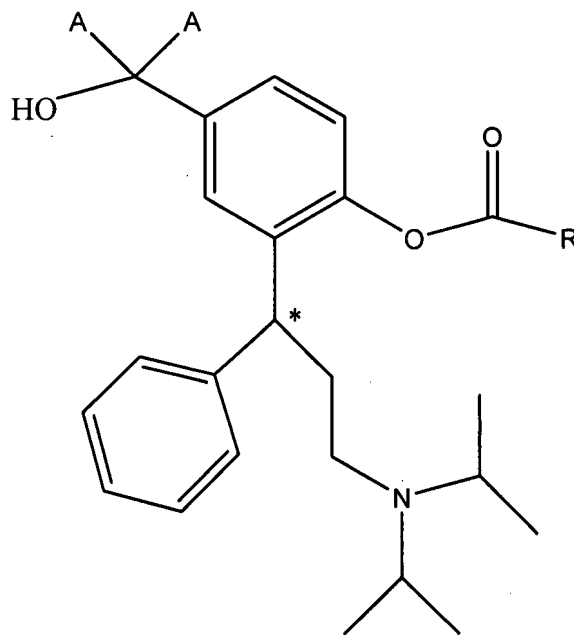
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1621

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 35 - 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claus et al (WO 99/58478 A1 November 18th 1999) and Arne et al (WO 94/11337 A1 May 26 1994).

Applicants claim a compound of **Formula (I)**:



Wherein, A is independently hydrogen or deuterium, R is 1-6- alkylor phenyl, and where the C-atom marked with a star "*" may be present in the (R)- configuration, the (S)- configuration or as a mixture. Further, R is selected from the group consisting of methyl, ethyl, ----- iso-butyl, pentyl and hexyl, and the compound in claim 35 is defined as 2-[3-(1,1-diisopropylamino)-1-phenylpropyl]-4-(hydroxymethyl) phenyl

Art Unit: 1621

isobutyrate. In claim 38 the compound further, specified as present in the (R)-configuration and in claim 39 the compound explicitly defined as (R)-2-[3-(1,1-diisopropylamino)-1-phenylpropyl]-4-(hydroxymethyl)phenyl isobutyrate (Fesoterodine).

Determination of Scope and content of the Prior Art (MPEP § 2141.01)

Claus et al teach (WO 99/58478 A1 November 18th 1999) novel derivatives of 3,3-diphenyl propylamines. Claus et al teach (\pm) – isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester and R – (+) – isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester. Claus thus teaches the compound or the formula I of the instant claims and the elected species, (see page 21, formula II and lines 9-10 WO 99/58478 A1).

Arne et al teach (WO 94/11337, May 26th 1994) novel 3,3-diphenyl propylamines, their use and preparation. Arne et al teaches the preparation of the compounds in high purity as assessed by chromatography > 99% (see page 11 lines 15-25).

Ascertainment of the difference between the Prior Art and Claims (MPEP §2141.02)

The difference between the instant compounds and Claus et al is that the instant compounds requires a high degree of purity of above 97 percent. Though Wieland teaches the preparation of the instant compounds does not explicitly teach the purity of the products to the extent of above 97 percent.

Finding of prima facie obviousness – rational and motivation (MPEP § 142-2143)

Accordingly, one of ordinary skill in the art would be motivated to prepare the instant compounds by modifying the process parameters from the teachings of Arne et al where one can use chromatographic technique to obtain highly pure organic compounds as taught by Arne in analogous type of compounds such as the 3,3-diphenyl propylamines,. The examiner contends that the combination of references is proper and an ordinary artisan would have had a reasonable expectation of success at the time of the instant invention to arrive at the instant compounds and hence it is prima facie.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalitha Nagubandi whose telephone number is 571 272 7996. The examiner can normally be reached on 6.30am to 3.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1621

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lalitha Nagubandi
Patent Examiner
Technology Center 1600

May 29th, 2007.



Samuel A Barts

Primary Patent Examiner
Technology Center 1600